

REMARKS/ARGUMENTS

In the Claims:

Claims 43-48, 50-55, and 64-83 remain pending in the present application. Claims 1-42, 49, and 56-63 have been canceled. Claims 43 and 64-78 have been withdrawn.

Allowable Subject Matter

The Examiner has indicated that claims 81-82 are allowable. Applicant appreciates the Examiner's indication of allowable subject matter. No changes have been made to claims 81 and 82.

Rejection of Claims 44-63 Under 35 U.S.C. § 112

The Examiner rejected claims 44-63 under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. More particularly, the Examiner asserts that the present application fails to adequately describe a liner for use in the present invention. As Applicant respectfully disagrees with the Examiner's assertion that claims 44-63 are not enabled by the specification, the rejection is respectfully traversed.

In reaching this conclusion, the Examiner refers to particular language of the 37 C.F.R. § 1.132 declaration of Mr. Raymond Francis that was submitted by Applicant on August 28, 2003. Specifically, the Examiner asserts that U.S. Patent 5,702,489, issued to Applicant, recites that some sort of lubrication should preferably be used to assist in donning and doffing of the prosthetic limb when a liner is not worn. And, since

paragraphs ten and eleven of the August 28, 2003 declaration state that the use of a lubricant was problematic when employed with early liner-based suction retention systems, the Examiner concludes that the use of a lubricant would also be problematic when used in conjunction with the present invention. Applicant respectfully disagrees with this conclusion. What the Examiner has overlooked is that paragraph ten of the aforementioned declaration also states that "... the socket design adopted for use with this liner made use of a one-way expulsion valve attached to a side of the socket, which one-way valve required an externally-located tube. This combination of socket and liner was problematic, because ... the one-way valve frequently became clogged by the lubricant on the outside of the liner ..." (emphasis added).

In contrast, the use of a lubricant is not problematic when using the present invention. In cases such as the one pointed out by the Examiner, only those portions of the residual limb or liner that will be in contact with the interior of the prosthetic socket need to receive lubrication. There is no need to lubricate the distal end of the residual limb or liner because it does not contact the prosthetic socket walls during donning or doffing of the prosthetic limb. Therefore, because the valve assembly of the present invention resides in the distal end portion of the prosthetic limb socket, it is substantially removed from contact with any lubricant applied to the sides of a residual limb or liner. This is not the case with the liner-based suction retention system referred to in paragraphs ten and eleven of the August 28, 2003 declaration. Rather, the design of the liner-based suction retention system referred to in paragraphs ten and eleven caused the lubricant to be scraped off of the liner and deposited into the valve assembly as the residual limb was inserted into the prosthetic socket.

With respect to the Examiner's comment that the August 28, 2003 declaration states that an acceptable liner for use with a BK prosthesis employing suction retention was not developed until the late 1990's, Applicant submits that what is meant by said comment is that a liner that could be satisfactorily used with previously known suction retention systems was not developed until that time. For purposes of clarity, the August 28, 2003 declaration should perhaps have stated that "an acceptable liner for use with BK prostheses employing various types of suction retention systems was developed in the late 1990's." One advantage of the design of the present invention is that it can be used with various types of liners - provided the liners are capable of producing an adequate seal within the socket. For example, the present invention can be employed even with the type of liner that proved problematic when used with the previously-developed suction retention system described in paragraph ten of the August 28, 2003 declaration. The present invention can also be used with other types of non-porous liners, such as the silicone liner described in U.S. Patent 5,702,489. Thus, what Declarant is actually asserting in the August 28, 2003 declaration is that, to Declarant's knowledge, no liner-based suction retention systems were known prior to the mid-1990's and, prior to the time of the present invention, existing liner-based suction retention systems proved to be unusable. Thus, not until creation of the present invention could suction retention be satisfactorily employed to retain a liner-covered residual limb.

With respect to the Examiner's assertion that the present application only tersely discusses the liner (sleeve) to be used in conjunction with the present invention, Applicant respectfully submits that a more detailed description is not necessary since,

as described above, the present invention is limited only to the extent that the liner selected for use must be capable of providing a seal with the interior of the socket (i.e., non-porous liners). U.S. Patent 5,702,489 specifically states that the sleeve (liner) provides a seal between the limb and the socket. (See column 5, lines 55-58). While U.S. Patent 5,702,489 describes the use of a silicone liner as an example, the present invention is not limited thereto. Rather, it should be realized from the general description and the specific example presented by U.S. Patent 5,702,489 that it is only necessary that the liner be constructed from a material that is itself capable of forming sealing contact with the interior walls of the prosthetic socket. Hence, while it is true that certain later-developed liners better facilitate donning and doffing of a prosthetic limb by making it easier to insert and remove the residual limb into a prosthetic socket thereof, the present invention is not limited to the use of these particular liners.

Therefore, Applicant respectfully submits that the liner (sleeve) recited in claims 44-63 does not require a description more detailed than that provided in the present application. As such, Applicant respectfully submits that claims 44-63 are enabled as required by 35 U.S.C. § 112.

Rejection of Claims 44-49 Under 35 U.S.C. § 112

The Examiner rejected claims 44-49 under 35 U.S.C. § 112, second paragraph, as failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention because the phrase "the liner-covered residual limb" lacks a proper antecedent basis. Applicant has amended the language of claim 44 to ensure that a proper antecedent basis exists therefor. Consequently, Applicant respectfully

submits that Examiner's 35 U.S.C. § 112 rejection of claims 44-49 may be properly withdrawn.

Rejection of Claims 44-49 Under 35 U.S.C. § 101

The Examiner rejected claims 44-49 under 35 U.S.C. § 101 because the Examiner asserts that claim 44 positively recites the residual limb itself, and such is unpatentable subject matter. Applicant has amended the language of claim 44 to read "... said base having a proximate surface positioned to face a distal end of the residual limb ...". Therefore, Applicant respectfully submits that claim 44 no longer positively recites the residual limb, and the Examiner's 35 U.S.C. § 101 rejection of claims 44-49 may be properly withdrawn.

Rejection of Claims 44, 45, 47, 49-53, and 56-58 Under 35 U.S.C. § 103(a)

The Examiner rejected claims 44, 45, 47, 49-53, and 56-58 Under 35 U.S.C. § 103(a) as being unpatentable over Sandmark (SE 8801686 A) in view of Fishman et al. (US 5,007,937), or Lenze et al. (US 5,376,131). Claims 56-63 have been canceled. As Applicant does not believe Sandmark in view of Fishman et al. or Lenze et al. to teach or suggest the subject matter of the remaining rejected claims, the rejection is respectfully traversed.

Sandmark does not teach or suggest the use of a any type of sleeve (liner) for placement over the residual limb of an amputee. As will be described in more detail below, Sandmark in view of Fishman et al. or Lenze et al. also fails to teach or suggest at this element of the rejected claims.

Fishman et al. simply teaches a modified stump sock and a method for its manufacture. The stump sock of Fishman et al. is of porous construction, and may be manufactured from materials such as nylon, orlon, cotton, or wool). (See column 1, paragraphs 56-59). Consequently, the sock (liner/sleeve) itself is incapable of being used with a suction retention system because the porous nature of the sock material will not permit a vacuum to be maintained in the prosthetic socket. Due to this inherent problem, the sock is modified by impregnating a small band of the porous sock material with a rubberized material. Once cured, this small band of rubberized material is said to provide a seal between the residual limb and the prosthetic socket. Thus, it is not the sock that provides sealing contact with the socket in Fishman et al. Rather, sealing is established as a result of contact between the interior of the prosthetic socket and the limited surface area provided by the raised area of rubberized material attached to the sock.

Lenze et al. teaches only that a prosthetic socket can be modified by inserting an elastic diaphragm (ring) into a prosthetic socket. The elastic ring may simply rest within the socket, or may be inserted into a groove created in the interior wall of the socket. The elastic ring is said to enable the portion of the socket residing below the ring to be evacuated.

Consequently, it can be seen that in contrast to the present invention, Sandmark in view of Fishman et al. or Lenze et al. does not teach or suggest a prosthetic limb or a prosthetic limb and valve assembly wherein the exterior surface of a non-porous sleeve is employed to provide sealing contact between the residual limb and the interior of the socket. The use of a sleeve as contemplated by the present invention is advantageous

because it makes it very unlikely that vacuum will be lost. This is not the case with the modified stump sock of Fishman et al., because producing and maintaining a seal relies solely on contact between the limited surface area of the rubberized material band and the interior of the socket. The stump sock itself is unable to maintain a seal.

Unlike the present invention, Sandmark also fails to teach or suggest a prosthetic limb or a prosthetic limb and valve assembly having a prosthetic socket wherein a channel or similar pathway for transferring air from within a prosthetic socket to the atmosphere remains unblocked by the residual limb until the residual limb is fully inserted into said socket. As can be seen in Sandmark, if the patients residual limb were fully inserted into the prosthetic socket, the opening in what the Examiner refers to as the base (7) would become blocked, thereby prohibiting the expulsion of any air still trapped in the socket or any air that leaks into the socket. The same appears to be true for Fishman et al. It also does not appear that Sandmark can be modified by Lenze et al. to alleviate this problem, as there is no teaching or suggestion in Sandmark to expel air from the bottom of the socket cavity. Additionally, while Lenze et al. appears to show a valve in the bottom of a prosthetic socket, there is no explanation of how air exiting the socket through the valve can be transferred to the environment once a prosthetic component assembly (such as an upright assembly) is attached thereto.

Also unlike the present invention, Sandmark fails to teach or suggest a prosthetic limb or a prosthetic limb and valve assembly wherein substantially no air pockets are left in the prosthetic socket once the residual limb has been fully inserted therein. As can be seen in Fig. 4 of Sandmark, it appears that when the residual limb is fully inserted thereto, an air gap remains between the tip of the residual limb and the bottom

of the socket cavity. The same would have to be true in Fishman et al., Figs 1 and 2 to the contrary, because the valve provided to remove air from the socket would become blocked by the residual limb before all of the air could be forced from the socket. Residual limb location is not expressly shown or described in Lenze et al.

Therefore, Applicant submits that there are material differences between the teachings of Sandmark in view of Fishman et al. or Lenze et al. and the subject matter of the rejected claims. As such, the Applicant respectfully submits that Sandmark in view of Fishman et al. or Lenze et al. cannot support a rejection of claims 44, 45, 47, and 49-53 under 35 U.S.C. § 103(a).

Rejection of Claims 50, 56, and 57 Under 35 U.S.C. § 103(a)

The Examiner rejected claims 50, 56, and 57 Under 35 U.S.C. § 103(a) as being unpatentable over Lenze et al. Claims 56-63 have been canceled. As Applicant does not believe Lenze et al. to teach or suggest the subject matter of the remaining rejected claim, the rejection is respectfully traversed.

The teachings of Lenze et al. have been discussed above. Claim 50 has been amended to more clearly describe the subject matter recited therein. Claim 50 now specifies that sealing contact for allowing the prosthetic socket to be evacuated is created by contact between a substantial portion of the outer surface of a non-porous sleeve and the interior of the prosthetic socket. Lenze et al. does not teach or suggest the use of any type of sleeve or liner. Lenze et al. does not even teach or suggest that sealing contact can be provided by contact between the skin of the residual limb and the interior of the prosthetic socket. Rather, Lenze et al. provides an elastic ring that may or

may not be removably attached to the interior of the socket. Lenze et al. also fails to teach or suggest how air can be removed from the socket through the valve once additional prosthetic components are attached to the end of the socket.

Therefore, Applicant submits that there are material differences between the teachings of Lenze et al. and the subject matter of the rejected claim. As such, the Applicant respectfully submits that Lenze et al. cannot support a rejection of claim 50 under 35 U.S.C. § 103(a).

Rejection of Claims 44, 47, 49, 50, 56, and 57 Under 35 U.S.C. § 103(a)

The Examiner rejected claims 44, 47, 49, 50, 56, and 57 Under 35 U.S.C. § 103(a) as being unpatentable over Catranis (US 2,530,285) in view of Fishman et al. or Lenze et al. Applicant has canceled claims 56-63. As Applicant does not believe Catranis in view of Fishman et al. or Lenze et al. to teach the subject matter of the remaining rejected claims, the rejection is respectfully traversed.

Catranis does not teach or suggest the use of a any type of sleeve (liner) for placement over the residual limb of an amputee. Catranis in view of Fishman et al. or Lenze et al. also fails to teach or suggest at this element of the rejected claims. The teachings of Fishman et al. and Lenze et al. have been discussed above. Whether combined with Fishman et al. or Lenze et al., the combination of references fails to teach or suggest a prosthetic limb or a prosthetic limb and valve assembly wherein the exterior surface of a non-porous sleeve is employed to provide sealing contact between the residual limb and the interior of the socket. The use of a sleeve as contemplated by the present invention is advantageous because it makes it very unlikely that vacuum will

be lost. This is not the case with the modified stump sock of Fishman et al., because producing and maintaining a seal relies solely on contact between the limited surface area of the rubberized material band and the interior of the socket. The stump sock itself is unable to maintain a seal. Lenze et al. does not teach or suggest a sleeve of any type.

Unlike the present invention, Catranis also fails to teach or suggest a prosthetic limb or a prosthetic limb and valve assembly wherein substantially no air pockets are left in the prosthetic socket once the residual limb has been fully inserted therein. As can be seen in Fig. 1 of Catranis, it appears that when the residual limb is fully inserted thereto, a substantial air gap is intentionally maintained between the tip of the residual limb and the bottom of the socket interior. The same would have to be true in Fishman et al., Fig.s 1 and 2 to the contrary, because the valve provided to remove air from the socket would become blocked by the residual limb before all of the air could be forced from the socket. Residual limb location is not expressly shown or described in Lenze et al.

Therefore, Applicant submits that there are material differences between the teachings of Catranis in view of Fishman et al. or Lenze et al. and the subject matter of the rejected claims. As such, the Applicant respectfully submits that Catranis in view of Fishman et al. or Lenze et al. cannot support a rejection of claims 44, 47, and 49-50 under 35 U.S.C. § 103(a).

Rejection of Claims 79 and 80 Under 35 U.S.C. § 102(b)

The Examiner rejected claims 79 and 80 Under 35 U.S.C. § 102(b) as being anticipated by Toles (US 980,457). Claim 79 has been amended to more clearly describe the subject matter recited therein. As Applicant does not believe Toles to teach the subject matter of claims 79 and 80, the rejection is respectfully traversed.

Toles fails to teach the use of a base or base-plate that provides an air-tight seal with the walls of a prosthetic socket interior. The sack (12) in contact with what the Examiner refers to as the base (tube (18)) is constructed of a flexible material. Thus, it is unlikely that it would be possible to provide a seal between the deformable sack (12) and the tube (18). Toles also fails to teach an attachment mechanism on the tube for allowing attachment of a prosthetic limb assembly to an exterior distal end of the socket. The structure referred to by the Examiner as the "upright assembly" is simply a threaded bolt/nut assembly to which the stump receiving sack is attached, and by which the sack can be stretched. The structure is contained entirely within the interior of the prosthetic socket, with the bolt portion thereof affixed (secured) to the interior wall of the socket. None of the structure passes through the socket wall, or is otherwise adapted to attach *any* type of component to the *exterior* distal end of the socket.

Therefore, the Applicant submits that there are material differences between the teachings of Toles and the subject matter of the rejected claims. As such, the Applicant respectfully submits that Toles cannot support a rejection of claims 79 and 80 under 35 U.S.C. § 102(b).

Rejection of Claim 83 Under 35 U.S.C. § 102(b)

The Examiner rejected claim 83 Under 35 U.S.C. § 102(b) as being anticipated by Surerus (DE 27 29 800 A1). Claim 83 has been amended to more clearly describe the subject matter recited therein. As Applicant does not believe Surerus to teach the subject matter of claims 79 and 80, the rejection is respectfully traversed.

Surerus fails to teach several elements of claim 83. First, Surerus fails to teach a port that allows the forced transfer of air to or from the open interior of a prosthetic socket. Rather, Surerus only allows air to be added to or removed from a sealed air bladder (22) that resides within a prosthetic socket. The port referred to by the Examiner in Figure 1 can be seen in Figure 3 to be attached to a tube (21) that is connected to the air bladder. Thus, any air forcibly introduced or removed through the tube is restricted to interaction with the interior of the air bladder. None of the air can be added to or removed from the open interior of the prosthetic socket. Consequently, Surerus also fails to teach that a residual limb can be drawn into or forced out of the prosthetic socket by the forced transfer of air to or from the port - as the expansion of the air bladder is unlikely to be of sufficient significance to force the residual limb out of the socket, and deflation of the bladder will have no drawing effect on the residual limb.

Surerus also fails to teach a prosthetic limb wherein substantially no air pockets remain within the prosthetic limb socket when the residual limb has been fully drawn into the socket by the forced removal of air therefrom. In fact, Surerus fails to teach a prosthetic limb wherein substantially no air pockets remain within the prosthetic limb socket when the residual limb has been fully inserted in any manner. Rather, as can be seen in Figure 3, the design of the prosthetic socket in Surerus allows a substantial air

pocket to exist between the residual limb and the bottom of the prosthetic socket when the residual limb is fully inserted therein.

Therefore, the Applicant submits that there are material differences between the teachings of Surerus and the subject matter of the rejected claim. As such, the Applicant respectfully submits that Surerus cannot support a rejection of claim 83 under 35 U.S.C. § 102(b).


CONCLUSION

Therefore, Applicant respectfully submits that the present application is now in condition for allowance, and entry of the present amendment and allowance of the application as amended is earnestly requested. If, however, the Examiner maintains his rejection, entry of the present amendment is respectfully requested as reducing the number of issues and placing this application in better condition for appeal.

Telephone inquiry to the undersigned in order to clarify or otherwise expedite prosecution of the present application is respectfully encouraged.

Respectfully submitted,

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